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510(k) Summary

Name of Sponsor:	NUTEK Orthopaedics, Inc. 301 SW 7th Street Ft. Lauderdale, FL 33301
510(k) Contact:	Peter Mincieli Vice President Operations 301 SW 7th Street Ft. Lauderdale, Florida 33315 peter@nutekortho.com Phone Office: (954) 312-8826 Phone Mobile: (954) 818-9204 Fax: (954) 495-8021
Proprietary Name:	NBX™ Non-Bridging External Fixator – Shoulder
Common Name:	External Fixation Devices – Bone Fixation Fasteners
Classification:	Class II per 21 CFR 888.3030; Multiple component metallic bone fixation Appliances and accessories
Device Product Code:	KTT – LXT
Substantially Equivalent Devices:	KMedic – K070561 – Smooth or Threaded metallic bone fixation fastener GexFix – K052605 – Smooth or Threaded metallic bone fixation fastener
Non-Clinical performance data:	Equivalence to accepted methods of treatment for this products indication of use is covered in other sections of this application.

510(k) Summary
continued

Device Description	The NBX™ Non-Bridging Fixator – Shoulder is provided sterile. The fixator consists of the body and with its proprietary locking mechanism and a multiple of threaded pins.
Intended Use:	The NBXTM Non-Bridging External Fixator – Shoulder, is used for external fixation, until healing, of open or closed fractures, mal-union, and non-unions of the proximal end of the humerus, to include sub-capital and/or fractures of the humeral head.
Material:	316LVM Stainless Steel (per ASTM F 138). Lexan HPS1R – complies with FDA Reg 21 CFR 177.1580

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

Nutek Orthopaedics, Inc.
% Mr. Peter Mincielli
Vice President of Operations
16771 SW 6th St.
Pembroke Pines, FL 33027

Re: K082833
Trade/Device Name: NBX™ Non-Bridging External Fixator - Shoulder
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, LXT
Dated: January 23, 2009
Received: January 28, 2009

Dear Mr. Mincielli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K082833

Device Name: The NBX™ Non-Bridging External Fixator – Shoulder

Indications For Use:

The NBX™ Non-Bridging External Fixator – Shoulder, is used for external fixation, until healing. This device is used for the fixation of open or closed fractures, mal-union, and non-union of the proximal end of the humerus to include sub-capital and/or fractures of the humeral head.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082833